

510(k) Summary of Safety and Effectiveness**Chromolite™ System****510(k) Number K 053324****Applicant:** Chromogenex Plc.**Address:** Units 1 & 2 Heol Rhosyn
Parc Dafen
Llanelli
Carmarthenshire
S. Wales
SA14 8QG
UK**Contact Person:** Mr. Chris Williams, Product Development Director**Telephone:** +44 (0) 1554 755444**Fax:** +44 (0) 1554 755333**Date prepared:** July 2005**Device Trade Name:** Chromolite™ System**Common Name:** Intense Pulsed Light (IPL)**Classification Name:** Laser Surgical Instrument 21 C.F.R § 878.4810.**Product Classification:** Class II device.**Product Code:** GEX

Legally Marketed Predicate Device: The Chromolite™ System is substantially equivalent in terms of technological characteristics, performance, intended use, indications for use and operator interface to;

- Orion lasers, Lovely system II (Harmony) (K033946)

System Description: The Chromolite™ is a Intense Pulsed Light-based medical device utilising xenon flashlamp technology to illuminate the dermis to offer light based therapies as listed in the indications of use. The Chromolite™ emits light at 390nm to 1200nm via a 50mm x 15mm waveguide at a repetition rate of 0.5Hz.

Performance Standards: The device complies with the European Medical Directive 93/42/EEC concerning medical devices, and will comply with voluntary standards UL60601-1:1996 when marketed in the U.S.

Indications for use: The Chromolite™ System is intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of plastic surgery and dermatology as follows:

- The treatment of moderate inflammatory acne vulgaris
- The treatment of benign pigmented epidermal lesions including dyschromia, hyper-pigmentation, melasma, ephelides (freckles)
- The treatment of cutaneous lesions including warts, scars, and striae.
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas, and spider angiomas, poikiloderma of civatte, leg veins and venous malformations.
- The removal of unwanted hair and to effect stable long-term or permanent hair reduction.

1 = Permanent hair reduction is defined as a long-term stable reduction in the number of hairs re-growing after a treatment regimen.

Conclusion: The Chromolite system is substantially equivalent to its predicate device cited above, and raises no new safety and/or efficacy issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 5 2006

Chromogenex Plc
c/o Marc M. Mouser
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
Camas, Washington 98607

Re: K053324

Trade/Device Name: Chromolite System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 21, 2005
Received: December 22, 2005

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a stylized, sweeping flourish at the end.

✓ Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053324

Device Name: Chromolite system _____

Indications for Use for Fitzpatrick skin types (I to V)

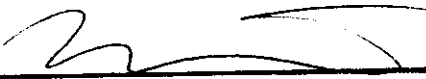
- The treatment of moderate inflammatory acne vulgaris
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles)
- The treatment of cutaneous lesions including warts, scars, and striae.
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas, and spider angiomas, poikiloderma of civatte, leg veins and venous malformations.
- The removal of unwanted hair and to effect stable long-term or permanent hair reduction.

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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